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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/751,702

01/05/2004

Elaine I. Tuomanen

044158/273011

2930

29312 7590 05/21/2008

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EXAMINER

MINNIFIELD, NITA M

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

05/21/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<p align="center"><b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b></p>	<p><b>Application No.</b> 10/751,702</p>	<p><b>Applicant(s)</b> TUOMANEN ET AL.</p>	
	<p><b>Examiner</b> N. M. Minnifield</p>	<p><b>Art Unit</b> 1645</p>	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 25 April 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: 5-7 and 15.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_  
13. ☐ Other: \_\_\_\_\_.

/N. M. Minnifield/  
Primary Examiner,  
Art Unit 1645

Continuation of 11. does NOT place the application in condition for allowance because: Applicants' arguments have been previously addressed. It is noted that Example 3 of the specification is directed to passive protection with anti-R2 antiserum. The claims are directed to vaccines comprising an antigen, therefore the claims are directed to active protection. Example 4 of the specification is directed to active protection with R1 (SEQ ID NO: 3) of serotype 4, however the claims are directed to vaccines comprising SEQ ID NO: 4, not SEQ ID NO: 3. The specification nor the art set forth any evidence that the portions of SEQ ID NO: 3 and SEQ ID NO: 4 that share similarity/identity produce the protective effect or have the protective epitopes. Applicants have asserted that since SEQ 4 possesses a significantly higher degree of structural similarity to SEQ 3 than that of SEQ 9, one of skill in the art would conclude that the success of SEQ ID NO:3 for cross protecting against the R6x serotype renders probable the ability of SEQ ID NO: 4 (as claimed by the present invention) to also produce a protective effect. However, the claimed invention must be enabled at the time the invention was made, not a "probable ability that SEQ ID NO: 4 would produce a protective effect". With regard to Bogaert et al, the reference states that other pneumococcal proteins that have shown potential as vaccine candidates are PspC (CbpA), for example, it is noted that the reference refers to the whole protein not a portion of the protein. PspC either contains a choline-binding domain like PspA and pneumolysin or a LPXTG motif like other gram-positive bacteria (citation omitted). This protein is supposed to bind secretory IgA and to interact with human epithelial and endothelial cells (citations omitted). Vaccination with PspC has shown to be protective against sepsis in mice. Moreover, antibodies directed against this protein have shown cross-reactivity against PspA (citation omitted). It is not yet clear though whether vaccination with PspC elicits protection against heterologous PspC type strains. The Pht family is one of cell surface-exposed homologous proteins representing histidine triad motifs of which several members have shown to elicit protection against different pneumococcal serotypes in a mouse sepsis model (citation omitted)." (Bogaert et al 2004, p. 2215) Protection against sepsis is not an indication that this polypeptide will protect against all pneumococcal infections nor is it to be considered to elicit species-wide pneumococcal infection protection.